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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/527,016	12/21/2005	Andreas Kubin	SONN:067US	1126

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EXAMINER

MELLER, MICHAEL V

ART UNIT	PAPER NUMBER
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1655

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	02/22/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary

Application No.

10/527,016

Applicant(s)

KUBIN ET AL.

Examiner

Michael V. Meller

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 12-34 is/are pending in the application.
- 4a) Of the above claim(s) 21-34 is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 12-20 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)
- Paper No(s)/Mail Date ____.

- 4) ☐ Interview Summary (PTO-413)
- Paper No(s)/Mail Date. ____.
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: ____.

DETAILED ACTION

Election/Restrictions

Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I, claim(s) 12-20, drawn to a composition.

Group II, claim(s) 21-29, drawn to a method of making the composition.

Group III, claim(s) 30-33, drawn to a first method of using the composition.

Group IV, claim(s) 34, drawn to a second method of using the composition.

The inventions listed as Groups I-IV do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons: the special technical feature is known in the art as is evidenced by the cited references herein including but not limited to Cody (see the claims).

During a telephone conversation with Mark Wilson on 2/7/2007 a provisional election was made with traverse to prosecute the invention of Group I, claims 12-20. Affirmation of this election must be made by applicant in replying to this Office action.

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Claims 21-34 are withdrawn from further consideration by the examiner, 37

CFR 1.142(b), as being drawn to a non-elected invention.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

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The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000. Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

Claims 12-14, 19, 20 are rejected under 35 U.S.C. 102(b) as being anticipated by Cody.

Cody teaches a soft gelatin capsule containing *Hypericum perforatum* (which contains hypericin) and polyvinylpyrrolidone (PVP), see col. 3, lines 20-30, col. 5, lines 50-end, the claims.

Claims 12-14, 19 are rejected under 35 U.S.C. 102(e) as being anticipated by Bombardelli et al. or Castillo et al.

Bombardelli teaches a tablet containing *Hypericum perforatum* (which contains hypericin) and polyvinylpyrrolidone (PVP), see paragraph 41, and the claims.

Castillo teaches that *Hypericum perforatum* and PVP are together in a tablet, see paragraphs 112 and 116.

Claim Rejections - 35 USC § 103

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The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 12-20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cody in view of JP 409262279.

Cody teaches a soft gelatin capsule containing *Hypericum perforatum* (which contains hypericin) and polyvinylpyrrolidone (PVP), see col. 3, lines 20-30, col. 5, lines 50-end, the claims.

Cody does not teach that the PVP is 10,000 to 40,000 g/mol.

JP teaches that PVP is routinely used for material which is suitable for the human body at a molecular weight of 20,000 to 150,000, see abstract.

Thus, it would have been obvious to one of ordinary skill in the art to use such a molecular weight of PVP since such a molecular weight range is well known to be used when contacting the human body. Further it would have been obvious to use the amounts claimed in the composition since the result-effective adjustment in conventional working parameters (e.g., determining an appropriate amount of the components within the composition) is deemed merely a matter of judicious selection and routine optimization which is well within the purview of the skilled artisan.

Claims 12-20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bombardelli et al. or Castillo et al. in view of Cody and JP 409262279.

Bombardelli teaches a tablet containing *Hypericum perforatum* (which contains hypericin) and polyvinylpyrrolidone (PVP), see paragraph 41, and the claims.

Castillo teaches that *Hypericum perforatum* and PVP are together in a tablet, see paragraphs 112 and 116.

Bombardelli and Castillo do not teach that the PVP has the claimed molecular weight, the other amounts in the claims, or that the composition is in a gel form.

Cody teaches a soft gelatin capsule containing *Hypericum perforatum* (which contains hypericin) and polyvinylpyrrolidone (PVP), see col. 3, lines 20-30, col. 5, lines 50-end, the claims.

JP teaches that PVP is routinely used for material which is suitable for the human body at a molecular weight of 20,000 to 150,000, see abstract.

Thus, it would have been obvious to one of ordinary skill in the art to use such a molecular weight of PVP since such a molecular weight range is well known to be used when contacting the human body as evidenced by JP. To use a gel composition instead of a tablet is also obvious since Cody makes it clear that either can be used, see col. 5, line 50-col. 6, line 60. Further it would have been obvious to use the amounts claimed in the composition since the result-effective adjustment in conventional working parameters (e.g., determining an appropriate amount of the components within the

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composition) is deemed merely a matter of judicious selection and routine optimization which is well within the purview of the skilled artisan.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael V. Meller whose telephone number is 571-272-0967. The examiner can normally be reached on Monday thru Thursday: 9:30am-6:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Terry McKelvey can be reached on 571-272-0775. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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A handwritten signature in black ink, appearing to read 'M. V. Meller', followed by a long horizontal line extending to the right.

Michael V. Meller
Primary Examiner
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